

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9191

Bartle, J.

January 8, 2014

Sandra K. Palmer ("Ms. Palmer" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether she has met her burden of proving that her

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Richard Palmer, Ms. Palmer's spouse, also has submitted a claim for derivative benefits.

claim was not based, in whole or in part, on any intentional material misrepresentations of fact.³

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In March, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Michael N. Rubinstein, M.D., F.A.C.C. Dr. Rubinstein is no stranger to this litigation. According to the Trust, he has signed at least 213 Green Forms on behalf of claimants seeking Matrix Benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

Based on an echocardiogram dated October 19, 2002, Dr. Rubinstein attested in Part II of claimant's Green Form that Ms. Palmer suffered from moderate mitral regurgitation and an abnormal left atrial dimension.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$578,687.⁵

In the report of claimant's echocardiogram, Dr. Rubinstein observed "moderate mitral valve regurgitation." Dr. Rubinstein, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. In addition, Dr. Rubinstein measured claimant's left atrium to be 4.1 cm in the antero-posterior systolic dimension. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or as a left atrial

4. Dr. Rubinstein also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

5. Under the Settlement Agreement, an eligible class member is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors necessary for a Level II claim.

antero-posterior systolic dimension greater than 4.0 cm in the parasternal long-axis view. See id. at § IV.B.2.c.(2)(b)ii).

In January, 2004, the Trust forwarded the claim for review by Christopher M. Kramer, M.D., F.A.C.C., F.A.H.A., one of its auditing cardiologists. In audit, Dr. Kramer determined that there was a reasonable medical basis for Dr. Rubinstein's findings that Ms. Palmer had moderate mitral regurgitation and an abnormal left atrial dimension.

Based on Dr. Kramer's findings, the Trust issued a post-audit determination awarding Ms. Palmer Matrix Benefits. Before the Trust paid Ms. Palmer's claim, we imposed a stay on the processing of claims pending implementation of the Seventh Amendment to the Settlement Agreement. See Pretrial Order ("PTO") No. 3511 (May 10, 2004). Prior to the entry of the stay, the Trust identified 968 Matrix claims that had passed audit as payable, which were designated as "Pre-Stay Payable Post-Audit Determination Letter ('PADL') Claims." Pursuant to Paragraph 5 of PTO No. 3883, the Trust was ordered to separate the Pre-Stay Payable PADL Claims into three categories. Of the 968 Pre-Stay Payable PADL Claims, the Trust alleged that 580 claims, including Ms. Palmer's, contained intentional material misrepresentations of fact. These 580 claims are commonly referred to as "5(a) claims." See PTO No. 3883, at ¶ 5 (Aug. 26, 2004).

Following the end of the stay, we ordered the Trust to review the 580 claims designated as 5(a) claims and issue new post-audit determinations, which claimants could contest. See

PTO No. 5625 (Aug. 24, 2005). Prior to the Trust's review of Ms. Palmer's claim, on November 22, 2006, this court approved Court Approved Procedure ("CAP") No. 13, which provided 5(a) claimants with the option either to submit their claims to a binding medical review by a participating physician or to opt-out of CAP No. 13. See PTO No. 6707 (Nov. 22, 2006). Ms. Palmer elected to opt-out of CAP No. 13.

The Trust therefore undertook to determine whether there were any intentional material misrepresentations of fact made in connection with Ms. Palmer's claim. As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of the echocardiogram system used during the performance of echocardiographic studies and the resulting interpretations submitted in support of Ms. Palmer's claim.⁶ As stated in his January 23, 2007 declaration, Dr. Kisslo determined, in pertinent part, that:

In Ms. Palmer's study, the use of high color gain and a very low frame rate, as well as the overmeasurement of the left atrial dimension are the result of deliberate choices and conduct engaged in by the sonographer performing this study and at a minimum, acquiesced in by the Attesting Physician. Each of these manipulations exaggerated or created the appearance of

6. In November, 2004, the Trust had provided Ms. Palmer with an "Expert Report" signed by Dr. Kisslo pursuant to Paragraph 11 of PTO No. 3883. In that report, Dr. Kisslo opined that "[e]xcessive and clinically unacceptable color gain was used while acquiring Ms. Palmer's echocardiogram, which resulted in increasing the apparent size of the alleged regurgitant flow The persons responsible for conducting the study and rendering a diagnosis relied upon a flow of short turbulence duration."

regurgitation, jet duration or a complicating factor. There is no responsible physiologic or hemodynamic construct under which this echocardiogram can be assessed as demonstrating moderate mitral regurgitation. Ms. Palmer has only trivial mitral regurgitation.⁷

Thus, notwithstanding Dr. Kramer's findings at audit, the Trust rescinded its prior post-audit determination letter and issued a new post-audit determination denying Ms. Palmer's claim based on its conclusion that there was substantial evidence of intentional material misrepresentations of fact in connection with the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Ms. Palmer contested this adverse determination.⁸ In contest, claimant argued that there was no evidence of any intentional material misrepresentations of fact made in connection with her claim. In support, she submitted videotaped statements under oath of Toni Kocun, the sonographer who performed Ms. Palmer's echocardiogram, and Gary Plotnick, M.D. In her testimony, Ms. Kocun stated that the color gain and frame rate used on Ms. Palmer's study were necessary in

7. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular place or <+ 5% RJA/LAA."

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Palmer's claim.

this particular instance due to claimant's size and makeup. Dr. Plotnick stated in his testimony that Ms. Palmer's study was typical of the quality of studies performed in doctors' offices during the time period and concluded that there was no substantial evidence of any intentional material misrepresentations made in connection with Ms. Palmer's claim. In addition, claimant noted that Dr. Kramer determined during his review that Ms. Palmer qualified for Matrix Benefits. She also included a letter from Dr. Rubinstein wherein he stated that claimant's echocardiogram was "technically adequate."⁹

Ms. Palmer also argued that there was a reasonable medical basis for Dr. Rubinstein's representation of moderate mitral regurgitation and an abnormal left atrial dimension. In support, claimant submitted a videotaped statement under oath of Dr. Rubinstein, wherein he identified several instances of supposed moderate mitral regurgitation and explained how any measurement of claimant's left atrial dimension would not alter his conclusion that Ms. Palmer had an abnormal left atrial dimension. In addition, claimant submitted Part II of Green Forms completed by Dr. Rubinstein, Duncan Salmon, M.D., F.A.C.C.,

9. Claimant also challenges Dr. Kisslo's credibility by reference to, among other things, Class Counsel's Disclosures and Request for Instructions with Respect to the Integrity of the Audit System. Class Counsel and all but one firm subsequently withdrew this submission after the adoption of certain Court Approved Procedures. We denied the motion of the remaining firms following briefing and argument. See PTO No. 6099 (Mar. 31, 2006).

and Mark M. Applefeld, M.D.¹⁰ Each cardiologist concluded that Ms. Palmer had moderate mitral regurgitation and an abnormal left atrial dimension.

The Trust then issued a final post-audit determination, again denying Ms. Palmer's claim. The Trust argued that claimant's contest failed to establish that there were no intentional material misrepresentations of fact made in connection with her claim. According to the Trust, Dr. Kramer's inability to detect any intentional material misrepresentations is not dispositive as the manipulations were intended to escape detection by a cardiologist who would not normally encounter them. The Trust also disagreed with claimant that a high color gain and low frame rate were necessary to obtain a usable echocardiogram. Moreover, the Trust contended that Dr. Plotnick's opinion was not probative because he was not aware of the specific techniques Dr. Rubinstein employed to exaggerate claimant's level of mitral regurgitation.

In addition, the Trust argued that claimant's contest failed to establish a reasonable medical basis for Dr. Rubinstein's representations of moderate mitral regurgitation and an abnormal left atrial dimension because the Green Forms of Dr. Salmon and Dr. Applefeld are merely cumulative. Finally, the Trust noted that while Dr. Plotnick reviewed claimant's

10. Dr. Salmon and Dr. Applefeld also are not strangers to this litigation. According to the Trust, they have appeared as experts for claimants in at least 29 and 24 contests, respectively.

echocardiogram, he did not opine as to claimant's level of mitral regurgitation or whether she had an abnormal left atrial dimension.

Claimant disputed the Trust's final determination and requested that her claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Palmer's claim should be paid. On September 26, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7439 (Sept. 26, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master, relying upon the arguments made in contest and stating that Dr. Plotnick did not opine on claimant's level of mitral regurgitation because the issue is whether there was any intentional material misrepresentation of fact made in connection with her claim. On April 14, 2008, the Trust informed the Special Master that it intended to rely upon the documents previously submitted and the arguments that it had already raised. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹¹ to review claims

11. A "[Technical] [A]dvisor's role is to act as a sounding (continued...)

after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for her claim.¹² Where the Trust's post-audit determination finds intentional material misrepresentations of fact, the claimant has the burden of proving that all representations of material fact in connection with her claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form either because of an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such

11. (...continued)

board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

12. Given our disposition with respect to claimant's level of mitral regurgitation, we need not determine whether there is a reasonable medical basis for finding that claimant suffered from one of the necessary complicating factors.

other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers with no intentional material misrepresentations of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed Ms. Palmer's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

The usual echocardiographic views were obtained. However, the study was not conducted in a manner consistent with medical standards. There was increased echo gain noted particularly in the apical views. There was obvious excessive color gain causing color artifact within the myocardial tissue and outside of the heart. There was a low frame rate with "stuttering" of cardiac images. An appropriate Nyquist limit of 67 cm per second was noted on this study. A parasternal short axis view rather than parasternal long axis view was inappropriately used to measure the left atrial dimension.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate claimant's echocardiogram and determined that there was no reasonable medical basis for the attesting physician's finding that Ms. Palmer had moderate mitral regurgitation. Dr. Vigilante explained, in pertinent part, that:

A minimal jet of mitral regurgitation was noted in the parasternal long-axis view. Visually, mild mitral regurgitation was noted in the apical four chamber and two chamber views. I digitized the cardiac cycles in the

apical four and two chamber views. In spite of excessive echo and color gain as well as a low frame rate, I was able to accurately planimeter the RJA in the mid portion of systole. The largest RJA in the apical four chamber view was 1.6 cm². The RJA in the apical two chamber view was less than 1 cm from the mitral valve plane and therefore only trace mitral regurgitation was noted in this view. I was able to accurately determine the LAA in this study. The LAA was 17.8 cm². Therefore, the largest RJA/LAA ratio was 9%. Most of the RJA/LAA ratios were less than 5%. The RJA/LAA ratio never came close to approaching 20%. There were no RJA or LAA measurements performed by the sonographer or submitted by the Claimant. I closely reviewed the color Doppler images at times 12:02:55, 12:04:30, 12:04:31, and 12:04:51. At these times, the color flow demonstrated low velocity and non-mitral regurgitant flow and was not indicative of mitral regurgitation. In real time, the mitral regurgitant jet was quite small and posterolaterally displaced within the left atrium close to the mitral valve plane. All RJA/LAA ratio determinations were 9% or less. These findings are similar to the formal echocardiogram report of April 1, 2002, performed about 6 months prior to the echocardiogram of attestation, which stated that there was evidence of very mild insufficiency.¹³

In response to the Technical Advisor Report, claimant argues that Dr. Vigilante should only have been asked to determine whether there was substantial evidence of any intentional material misrepresentations of fact made in

13. Dr. Vigilante also determined there was no reasonable medical basis for Dr. Rubinstein's representation that claimant had an abnormal left atrial dimension.

connection with her claim, not whether there was a reasonable medical basis for Dr. Rubinstein's representations.¹⁴

After reviewing the entire show cause record, we find claimant has not established a reasonable medical basis for the attesting physician's finding that Ms. Palmer had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of the Settlement Agreement and the Audit Rules, we previously have explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640, at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

14. Claimant also asserts, without any support or specificity, that Dr. Vigilante should not review any claims submitted by Ms. Palmer's counsel because Dr. Vigilante was "on the opposite side of a few medical malpractice cases with one of the reviewing cardiologists in this matter." In the absence of even a suggestion that these cases affected Dr. Vigilante's review of Ms. Palmer's echocardiogram, we need not address this issue.

Here, Dr. Kisslo and Dr. Vigilante each found that the echocardiogram of attestation was not conducted in a manner consistent with medical standards because, among other things, the echocardiogram settings included a high color gain and a very low frame rate. Notwithstanding these deficiencies, Dr. Kisslo and Dr. Vigilante determined that Ms. Palmer's echocardiogram demonstrated, at most, only mild mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's opinion that Ms. Palmer had moderate mitral regurgitation. Specifically, he explained that "the largest RJA/LAA ratio was 9%" and that "[m]ost of the RJA/LAA ratios were less than 5%."

Claimant's primary substantive challenge with respect to the measurement of her level of mitral regurgitation is the statement of Dr. Rubinstein, who identified several frames during which he contended moderate mitral regurgitation was demonstrated. Dr. Vigilante, however, specifically reviewed these frames and determined, "At these times, the color flow demonstrated low velocity and non-mitral regurgitant flow and was not indicative of mitral regurgitation. In real time, the mitral regurgitant jet was quite small and posterolaterally displaced within the left atrium close to the mitral valve plane." Despite responding to the Technical Advisor Report, claimant did not address this finding or identify any particular error in Dr. Vigilante's analysis. Mere disagreement with the Trust's

expert and the Technical Advisor is not sufficient to meet claimant's burden of proof.¹⁵

We conclude, based on our review of the entire record, that there is no reasonable medical basis for Dr. Rubinstein's representation that claimant had moderate mitral regurgitation. Thus, we need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with Ms. Palmer's claim.¹⁶

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Palmer's claim for Matrix Benefits and the derivative claim submitted by her spouse.

15. For these reasons as well, the opinions of Dr. Salmon and Dr. Applefeld do not aid claimant in meeting her burden of proof.

16. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625, at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists simply because a claim has previously passed audit.